TECHNICAL REVIEW DOCUMENT for OPERATING PERMIT 950PB0150

to be issued to:

Roche Colorado Corporation **Boulder Facility**Boulder County

Source ID 0130025

Cathy Rhodes February, 2000

I. PURPOSE:

This document will establish the basis for decisions made regarding the applicable requirements, emissions factors, monitoring plan and compliance status of emission units covered by the operating permit proposed for this site. It is designed for reference during the review of the proposed permit by the EPA, the public, and other interested parties. This narrative is intended only as an adjunct for the reviewer and has no legal standing. The conclusions made in this report are based on information provided in the original application submittal February 23, 1996, subsequent supplemental technical submittals, and previous inspection reports.

Any revisions made to the underlying construction permits associated with this facility in conjunction with the processing of this operating permit application have been reviewed in accordance with the requirements of Regulation No. 3, Part B, Construction Permits, and have been found to meet all applicable substantive and procedural requirements. This operating permit incorporates and shall be considered to be a combined construction/operating permit for any such revision, and the permittee shall be allowed to operate under the revised conditions upon issuance of this operating permit without applying for a revision to this permit or for an additional or revised Construction Permit.

II. SOURCE DESCRIPTION:

This facility is located in Boulder, Colorado. Boulder is classified as nonattainment for carbon monoxide and particulate matter less than 10 microns (PM₁₀). Federal Class I designated areas within 100 kilometers of the plant include Rocky Mountain National Park, Eagles Nest Wilderness Area, and Rawah Wilderness Area. There are no affected states within 50 miles.

This facility consists of a manufacturing facility for pharmaceutical intermediates, bulk pharmaceutical and some non-pharmaceutical chemicals. All products are bulk and are shipped to other corporate sites for either final chemical transformations or formulation into the final product for patient use. Production of a given compound is performed by a process equipment train. A process train will be composed of selected reactors, filters,

distillation columns, etc as needed to produce the compound. The equipment may be located in various plant buildings. Some of the equipment may be used only in one process train, while other equipment may be repeatedly used in several process trains. The equipment in these trains is cleaned and reconfigured to make multiple batches of different products.

In addition to the production areas, the facility also includes a wastewater industrial pretreatment plant, an above-grade buried tank farm, and utility systems needed for production, space heating and cooling.

The facility was originally issued five construction permits. In addition, some activity areas were grandfathered from construction permit requirements, and others were in process of being permitted. Roche Colorado Corporation requested that all activities be combined into one permit, which would contain an over-all total VOC emission limit (a plant wide limit) for all sources at the facility. Instead of issuing a new Construction Permit, the plant wide limit is incorporated directly into the Operating Permit. This avoids duplication of Division effort and public notice requirements. The plant wide limit gives Roche Colorado Corporation the flexibility to allow for fluctuations in production rates at the various processes within the facility without undergoing New Source Review (PSD/NSR), as long as the overall plant emission limit is not exceeded, and no new equipment is added (except as allowed in Alternate Operating Scenarios). In addition, Roche may move existing equipment within the facility, and may manufacture new products, provided certain requirements are met, as described later in this document.

Facility wide emissions are as follows:

Pollutant	Potential (TPY)	Actual (TPY)
Particulate Matter (PM)	2	<1
PM ₁₀	2	<1
Nitrogen Oxides (NO _x)	20	8
Sulfur Dioxide (SO ₂)	<1	<1
Volatile Organic Compounds (VC	OC) 375	250
CO	11	7
HAPs	N/A	124

HAPs consist mainly of toluene, hexane, and methanol.

Potential VOC emissions are based on the summation of actual emissions for a representative two year operating period for each activity area. Potential emissions for the other pollutants are based on construction permit limits. The potential emissions are the permitted limits incorporated into the operating permit. Actual emissions are based upon 1997 APEN data. Roche Colorado Corporation agreed to a plant-wide emission limit below their previous allowable emissions in order to allow for flexibility in operations, as described above.

III. Compliance Monitoring Plan

Regulation No. 3, Part C and 40 CFR Part 70 require the Operating Permit to contain specific procedures and methods for demonstrating and monitoring compliance. Roche Colorado submitted a comprehensive Compliance Monitoring Plan for Division approval, which sets forth emissions calculation procedures, the baseline operating parameters for control equipment and associated monitoring methods to ensure proper operation of the equipment, and how compliance with specific regulations such as MACT will be monitored and demonstrated. This document is included as an Appendix to the Operating Permit. The specific conditions in the Operating Permit reference the most recent Division-approved Compliance Monitoring Plan. The permit provides that this Plan may be updated as Roche gains additional knowledge with regard to sources at the facility, or as the Division and/or Roche deem necessary to ensure and monitor compliance.

Regarding emission calculation procedures, AP-42 factors, or Roche's knowledge regarding emissions, may change based on new or improved data, or the addition of a new product. A logical concern is what happens if the use of the new emission factor or calculation procedure results in the source being out of compliance with a permit limit. For this operating permit, the emission calculation procedures contained in the Plan are considered to be fixed until changed through the proper procedures. It is the responsibility of the permittee to be aware of changes in the factors and procedures and to notify the Division in writing of impacts on the permit requirements when there is a change in factors or procedures. For changes regarding emission calculation procedures or factors, the Division will work with the permittee to address the situation. Specific procedures for adding emission factors for new processes are described under Operational Flexibility, below.

The Division will review for approval any future proposed changes to the Plan, and the changes will be processed through the applicable permit modification procedures (administrative, minor, or significant modification). This will ensure that any significant modifications to the compliance demonstration procedures will undergo public review.

IV. Emission Sources

The following sources are specifically regulated under terms and conditions of the Operating Permit for this site:

Facility-Wide Limit

Activities occurring at this facility are as follows.

P010 Consists of the following manufacturing areas:

Plant 1 North: The north end of Plant 1 has historically manufactured non-pharmaceutical products. The permit prohibits manufacture of pharmaceutical products. Emissions are controlled by condensers. In addition, the equipment is connected to the thermal oxidizer. This area is grandfathered from Construction Permit requirements.

Plant 2 North: d,l-acid (an intermediate in the synthesis of naproxen) has traditionally been manufactured in this area, however, the equipment in this area will have multi-purpose capabilities (i.e., the equipment can be configured to make a variety of products, sometimes simultaneously). In addition to d,l-acid, Plant 2 North will also be configured to make Orlistat, an anti-obesity drug. Condensers control VOC emissions. In addition, equipment located in the Plant 2 North area will be connected to the thermal oxidizer. The Division was in process of issuing a Construction Permit for this area. The applicable requirements are incorporated directly into this operating permit.

Plant 2 Center - The Division was in process of issuing a Construction Permit for this area. Subsequently, the permittee has ceased production in this area, but will resume production of new products in the future. Pharmaceutical and non-pharmaceutical production may occur in this area. Condensers control VOC emissions. In addition, full-scale production equipment used in this area will be connected to the thermal oxidizer per the applicable requirements of the permit. The area is included in this Operating Permit, and new processes may occur in the area, as described under operational flexibility, below. The applicable requirements are incorporated directly into this operating permit.

Multipurpose Area: The Multipurpose area includes all of Plant 3, Plant 1 South, Plant 1 Center and the Warehouse dryers. The process trains are used to manufacture pharmaceutical products, including Ganciclovir, NOG-1 and NOG-0 (intermediates of Naproxen) and Ro 61-4022. The equipment can also manufacture non-pharmaceutical products such as Cyclopentadiene. Equipment in the trains is cleaned and reconfigured to make multiple batches of different products. Condensers control VOC emissions. In addition, the equipment is connected to the thermal oxidizer. Initial Approval Construction Permit 93BO833 was issued for this area. The Division was in the process of issuing Final Approval. Roche requested addition of the following processes: chloroalcohol, hydroxyester, aminoalcohol, hydroxycarbamate, other specific intermediates of ganciclovir, and valgenciclovir, and thiocarbaester (TCE) and associated solvent recovery - TCE is an intermediate in the manufacture of drugs used in treatment of pediatric AIDS and HIV patients. No new equipment is necessary in the existing multipurpose train, and VOC emissions remain below the permitted VOC level. These additions are included in the operating permit.

T100 - Aboveground Buried Tank Farm: A total of 14 tanks exist in this tank far, 7 of which are filled with sand and are no longer useable. The tanks were constructed above grade (ground level) and then covered by mounding soil over the tanks. The soil cover

provides a stable temperature for the tank contents. The material stored in the tanks is used for the various production processes in the plant. The tanks are filled by truck delivery. Final Construction Permit 84BO333V was issued for these sources.

B001 - Boilers: Three natural gas boilers provide hot water and steam as required for production processes and climate control. Final Approval Construction Permit 89BO010 was issued for these sources.

W001 - Wastewater Plant: An industrial wastewater pretreatment plant is used to treat wastewater from the facility before discharge to the municipal wastewater system. The treatment process consists of flow equalization, pH adjustment, primary clarification, activated sludge aeration, and secondary clarification. Final Approval Construction Permit 90BO061 was issued for this source.

S500 - Environmental Control System: The Environmental Control System (ECS) collects the VOC emissions from various process equipment and delivers the emissions to a thermal oxidizer for destruction. Initial Construction Permit 95BO1113 was issued for this source. The ECS was installed pursuant to an agreement with the City of Boulder and Boulder Residents for the Elimination of Air Toxic Emissions (BREATHE). The ECS is not required to meet any federal or state regulatory requirement at this time, however, the ECS may be used instead of condensers or other methods to meet regulatory requirements.

Facility Wide Applicable Requirements - Applicable requirements are set forth in the regulations and the following Construction Permits: 93BO833, 84BO333V , 89BO010, 90BO061, and 95BO1113. The Construction Permit applicable requirements were modified or deleted as necessary, as described below, and incorporated directly into the Operating Permit through a combined construction/operating permit process.

Colorado Regulation No. 7

Section III - General RACT Requirements for Storage and Transfer of VOCs

- Maintain and operate tanks to prevent vapor loss
- Submerged or bottom filling equipment

Monitoring - (Note: All monitoring methods listed in this document are those as required in the current Division approved Compliance Monitoring Plan.) Inspection 3 days/week.

Section IV - RACT for Storage of Highly Volatile Organic Compounds

Requires storage in pressure tanks to prevent vapor loss

Monitoring - Inspections 3 days/week.

Section V - Disposal of VOCs

Prohibits disposal of VOCs by evaporation or spillage unless RACT is used.

Monitoring - Roche does not dispose of VOCs by evaporation or spillage.

Section XIV - RACT for Pharmaceutical Synthesis

 Requires control of emissions from certain vents - sets forth condenser outlet temperatures

Monitoring - A list of condenser outlet temperatures which meet the control requirement is maintained. In addition, emissions may be controlled by the ECS (see Alternate Operating Scenarios/Operational Flexibility, below).

Requires reduction of VOC emissions from certain processes to 33 lbs/day

Monitoring - Calculations are maintained to demonstrate compliance

 Use vapor balance system for certain tanks storing VOCs with high vapor pressure

Monitoring - One-time leak check of vapor balance system, in the event high vapor pressure solvent is stored in the future

- Enclose certain pieces of equipment
 Monitoring Inspection 3 days/week
- Cover in-process tanks
 Monitoring Inspection 3 days/week
- Repair leaks
 Monitoring Inspection 3 days/week
- Control techniques and work practices to minimize fugitive emissions
 Monitoring Employees trained in standard operating procedures

<u>Uncontrolled Process Equipment (Consent Order, Section II.B.2, February, 1993</u>

In February 1993, Roche Colorado Corporation (then Syntex) and the Division signed a Consent Order which required Roche to provide certain information and implement certain practices in order to ensure compliance with Colorado Regulation No. 7 (RACT for VOC emissions). In the order, the parties agreed that Section II.B.2 would be incorporated and made part of the operating permit for this facility.

Equipment with potential to emit less than 15 lbs of VOC per day are exempt from

the RACT requirements of Regulation No. 7, Section XIV (Pharmaceutical Synthesis). In order to ensure that the potential to emit of certain equipment at the Roche Colorado facility is less than 15 lbs/day, Roche follows a program outlined in the Consent Order of calculation emissions for each process using the subject equipment. The equipment is then labeled with the process or "batch in process" name. Once the equipment has been shown by calculation to be within the 15 pound per day limit for a specific process, the Division need only examine the label on the equipment to verify that equipment is in use for an approved process and is in compliance.

40 CFR Part 63, Subpart I - National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks, and Subpart H - National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks

This subpart applies to pharmaceutical production facilities which use carbon tetrachloride or methylene chloride. It requires inspection for detection and repair of equipment leaks. Roche currently does not use either carbon tetrachloride or methylene chloride. The requirements are included in the Operating Permit in the event Roche uses these chemicals in the future. In addition, Roche has volunteered to implement the requirements of this subpart for all areas, except that monitoring, recordkeeping, and reporting methods are as set forth in an agreement with the City of Boulder. Following the requirements allows Roche to assume 80 to 90 percent reduction when estimating fugitive emissions.

Note: The compliance date for Subpart GGG, the pharmaceutical MACT, is September 21, 2001. After this date, affected sources that are subject to Subpart I and Subpart GGG will no longer be required to comply with Subpart I. In addition, the permittee has requested that after the compliance date of Subpart GGG, the components for which they are voluntarily implementing a leak detection and repair (LDAR) program be subject to Subpart GGG requirements instead of Subpart I requirements.

Monitoring - Inspection schedules and repair requirements are set forth in Subparts H and I.

<u>40 CFR Part 63, Subpart GGG - National Emission Standards for Pharmaceuticals</u> Production

The compliance date for this subpart is September 21, 2001. The compliance date may change if the EPA revises the regulation in the interim. The rule sets forth specific requirements and monitoring procedures for process equipment, storage tanks, and wastewater treatment. The rule also allows for certain process changes (known as a "Change Management Strategy" (CMS)") to be made, provided certain procedures and recordkeeping and reporting requirements are met. The permittee

will submit a plan for implementing the CMS and the operating permit will be revised or modified to include the CMS plan, specific MACT requirements, and monitoring provisions.

<u>Waste Solvent</u> - This requirement was included in some of the Construction Permits. The requirement is included as applicable to all production facilities covered by the operating permit.

 Requires storage to prevent public access, to avoid release of toxic substances to the atmosphere

Monitoring - Fenced property limits public access.

VOC Emission Limit

As described above, the operating permit sets a facility wide VOC emission limit in order to provide Roche operational flexibility. Actual VOC emissions from a representative two year production period were determined for each production area. Average annual emissions for each area were then summed to determine the facility-wide emission limit. The ECS has not operated for two years, therefore the Construction Permit emission limit was used. For areas with Construction Permits, actual emissions are less than the Construction Permit emission limits. Actual emissions, not permitted limits, were used to establish the facility wide emission limit. Representative production years for the areas occurred from 1993 to 1998.

Monitoring - The permittee will maintain records of chemicals produced and other information needed to estimate emissions.

<u>Initial Approval Construction Permit 93BO833</u> was issued for the multipurpose area. The Division was in process of issuing Final Approval. Applicable requirements are as follows.

Construction Permit 93BO833

- Limits opacity to 20% (Note: This source does not emit emissions which would cause visible emissions, therefore, this condition is not included in the Operating Permit for this or other VOC emitting sources)
- Equipment list to be posted in Plants 1 and 2 (replaced with up-todate log, as described under Operational Flexibility, below)
- Limits VOC emissions to 179.9 tons/year (included in facility-wide limit actual average emissions were 125.4 tons/year)
- Allows revision of emission calculation method (see discussion under Operational Flexibility, below)
- Requires wastewater testing (this requirement is also included in Construction Permit 90BO061, for the wastewater treatment plant the requirement is not included as a facility-wide requirement, but is

- included for the wastewater treatment plant)
- Prior to Final Approval, one of the dryers in the warehouse is to be replaced with a larger unit, unless Roche demonstrates that the VOC emission limit can be met without the replacement (This requirement is removed in the operating permit. Correspondence from Roche (the Syntex) in March, 1997 indicated that Syntex determined that a new dryer would not be necessary and would not be added under the 93BO833 permit modification. It also indicated that the emission limit in the 93BO833 permit was based upon the process in the existing equipment configuration, not upon a potential new dryer. Therefore, meeting the emission limit is done through operating the existing equipment.)
- Roche shall inform the Division in writing prior to replacing the Rosenmund filter in Plant 1 with a new dryer (This condition is removed from the operating permit. The Rosenmund filter has not been replaced and Roche does not intend to do so at this time. If the Rosenmund is replaced in the future, Roche will use the appropriate permit modification procedures at that time.)
- Waste solvent shall be stored to prevent public access (this requirement is included in the operating permit, to apply to all areas within the facility)
- Allows substitution of one compound for another provided the emission limit is met, equal or less relative toxicity, and a revised APEN is filed. The Division has 45 days to approve or disapprove the change. (This requirement is revised and applies to all areas within the facility, as described under Operational Flexibility, below.)

T100 - Storage Tank Farm

Applicable Requirements - In addition to the facility-wide applicable requirements, the following requirements apply.

Construction Permit 84BO333V

- Limits opacity to 20% (Note: This source does not emit emissions which would cause visible emissions, therefore, this condition is not included in the Operating Permit)
- Limits types of materials that may be stored (This list of materials is included in an Appendix to this Operating Permit, to allow for changes, as described under Operational Flexibility, above)
- Limits storage of dimethoxymethane to tank T-14, and limits vapor

pressure of materials stored in tanks other than T-14 (these restrictions are in place because dimethoxymethane has a vapor pressure which requires a vapor balance system under the RACT requirements, all other tanks are restricted to materials for which the vapor pressure would not require a vapor balance system - In addition, the specific reference to dimethoxymethane is deleted, to allow for storage of other chemicals with high vapor pressure in tank T-14)

- Limits total material throughput (This requirement is deleted to allow for flexibility under the facility-wide emission limit - The permittee will track the amount of material stored for emission calculation purposes)
- Limits VOC emissions to 8.76 tons/year, on a twelve month rolling total (*This limit is included in the facility wide emission limit Actual average annual emissions were 1 ton/year*)
- Colorado Regulation No. 7: Sections III and XIV, as described under the facility wide applicable requirements, above
- Sets forth specific monitoring/recordkeeping requirements

Monitoring - Records of type, amount, vapor pressure of each material stored. Also records of in which tank each material is stored. Monitoring for other applicable requirements will occur as described under the facility wide applicable requirements, above.

B001 - Boilers

Applicable Requirements - In addition to the facility wide applicable requirements, the following apply:

Construction Permit 89BO010

- Limits opacity to 20%
- Limits emissions on a tons/year basis (Note: These emission limits were calculated based on emission factors from the EPA's AP-42, Section 1.4, October 1996. The EPA published revised emission factors for Section 1.4 in March, 1998. The emission limits are revised in the Operating Permit to reflect the new emission factors. The emission limits for PM, NO_x, and VOC went down. VOC emissions are included in the facility-wide limit. PM₁₀ emission limits were not included in the Construction Permit, and were estimated and added to the Operating Permit. The CO emission limit increased. Based on modeling information contained in the Construction Permit file, this increase in the CO emission limit should not cause or contribute to a violation of the ambient air standards. The increase of 5 tons CO per year does not represent a significant increase for NSR nonattainment review purposes.)
- Limits natural gas consumption on an annual basis

• Requires records of hours of operation for each boiler on a monthly basis, and records of natural gas use on a rolling 12 month basis. (Note: natural gas usage is monitored using a single fuel meter for all three boilers; because the emission factors are the same for each boiler, the total emissions are the same regardless of the combination of operating hours of each boiler. Therefore, the requirement to record the hours of operation for each boiler is deleted from the Operating Permit)

Colorado Regulation No. 1

- Limits opacity to 20%, except for 30% during certain operating conditions (II.A.1 & 4)
- Limits PM emissions from fuel burning equipment

Colorado Regulation No. 6, Part B (state-only requirement)

This regulation applies to units constructed after 1/30/79, therefore it applies to the two Cleaver Brooks boilers.

- Limits PM emissions from fuel burning equipment (II.C.2)
- Limits opacity to 20% (II.C.3), except during startup, shutdown, or malfunction

Streamlining of Applicable Requirements - The Regulation No. 6 PM emission limit is streamlined out. This limit applies at all times, except during startup, shutdown, or malfunction. The Regulation No. 1 PM emission limit is equivalent, except that it applies at all times, therefore it is more stringent than the Regulation No. 6 requirement.

Monitoring Plan - Records of the amount of natural gas usage on a monthly basis will be used to monitor compliance with the fuel consumption limits and the emission limits. Compliance with opacity limits and the Regulation No. 1 PM limit is assumed when natural gas is used as fuel.

W001 - Wastewater Treatment Plant

Applicable Requirements - In addition to the facility wide applicable requirements, the following requirements apply.

Construction Permit 90BO061

- Limits opacity to 20%(Note: This source does not emit emissions which would cause visible emissions, therefore, this condition is not included in the Operating Permit)
- Limits VOC emissions to 10.3 tons/year on a rolling twelve month basis (included in facility wide limit - actual average annual emissions were 9 tons/year)
- Sets forth specific monitoring and recordkeeping requirements

Colorado Regulation No. 7, II.C.1

 Reasonably Available Control Technology (RACT) must be used at this source. The Division determined that the process design represents RACT for this source.

Monitoring - The permittee samples the wastewater effluent quarterly and keeps records of flow rate.

S500 - Environmental Control System

Applicable Requirements - In addition to the facility-wide requirements, the following requirements apply.

Construction Permit 95BO1113

- Limits opacity to 20%
- Limits emissions on a lb/hour and tpy basis (annual VOC emissions are included in the facility-wide limit)
- Limits natural gas consumption rate
- Colorado Regulation No. 6, Part B, VII, Standards of Performance for incinerators (state-only requirement)

Limits PM emissions to 0.1 gr/dscf

Limits opacity to 20%

Source is subject to recordkeeping, testing, reporting requirements of 40 CFR Part 60, Subpart A

Colorado Regulation No. 1

Limits PM emissions to 0.1 gr/dscf (III.B.2.a)

Limits SO_2 emissions to 2 tons/year (the Construction Permit notes that compliance with the Construction Permit SO_2 emission limit of .04 ton/year represents compliance with the Regulation No. 1 SO_2 emission limit.

Limits opacity to 20%, except during certain operating conditions, when the opacity limit is 30%

- Requires 95% destruction of VOCs
- States which processes must be exhausted to the thermal oxidizer (This condition has been moved to the permit section covering "Pharmaceutical and Non-pharmaceutical Production" because this condition describes the control requirements for those production areas, rather than being a requirements for the thermal oxidizer's performance. In addition to being moved, this requirement has been modified to reflect current regulatory control requirements for these production areas. It has been revised to allow use of the thermal oxidizer to comply with RACT provisions and to account for the thermal oxidizer control efficiency in calculating actual emissions with the VOC limit. The recordkeeping requirements regarding downtime of the collection system and the thermal oxidizer remain in place.)
- Requires a compliance test (this test has been completed, and the

- information was used to devise the required compliance plan)
- Requires submittal of a compliance plan and recordkeeping format This requirement has been completed.
- Isolators are subject to Regulation No. 7, Section III requirements (Storage and Transfer of VOCs) - This requirement is deleted from the operating permit - As planned, the isolators would have stored VOCs, but as constructed, the isolators store water, not VOCs.

Monitoring - Compliance with opacity limits and the PM grain loading limit is assumed when natural gas is used as fuel. Compliance with the VOC emission limit is monitored by measuring temperature and other parameters at the thermal oxidizer. Compliance with other pollutant emission limits is assumed when the natural gas annual consumption limit is met. For the thermal oxidizer, thermocouples measure the combustion zone temperature and the exhaust gas temperature. A Distributive Control System monitors the valve positions to indicate downtime for the thermal oxidizer and collection system. Flow meters measure natural gas flow and exhaust (stack) gas flow. In addition, a stack test is required once per permit term to monitor control efficiency.

Small Parts Cleaners - Cold cleaners are used at the facility.

Applicable Requirements - These sources are exempt from Construction Permit requirements, but are subject to Colorado Regulation No. 7, X, RACT for Use of Solvents for Degreasing and Cleaning, as follows.

- No more than 20% loss of waste or used solvent during transfer
- Store waste and used solvent in closed containers
- Requirements for cleaner covers
- Drainage requirements
- Operational requirements

(Emissions from the cold cleaners are included in the facility wide total.)

Monitoring - Because small remote reservoir units meet the requirements of Regulation No. 3, Part A, Section II.D.4.b.(vi) these units are in compliance with the requirements of Regulation No. 7, Section X.B by design. Annual certification by the Responsible Official that these units have not been modified is adequate to demonstrate compliance with the applicable requirements for these units. For units that are not small remote reservoir units, the Compliance Monitoring Plan will contain at a minimum the requirements in Regulation 7, Section X.A and B. In addition the Division will require the source to perform an annual audit to ensure that the Plan incorporates, at a minimum, the requirements of Regulation No. 7, Section X.B and that operations are being performed within the requirements of the Plan. The source shall be required to certify annually that waste solvents are being handled appropriately as required by Regulation No. 7, Section X.A.3 and 4.

Emission Factors for All Sources - Emissions from the following steps within the process for each product are estimated using the EPA's "Control of VOC Emissions from Manufacture of Synthesized Pharmaceutical Products:" Charging, Evacuation, Nitrogen or Air Sweeps, Temperature Increase Steps, and Gas Evolution Steps. Distillation emissions are estimated using the EPA document and mass balance. Drying emissions are estimated using a mass balance approach. Fugitive emissions from cleaning, leaks and other operations are included in emission estimations. Equipment leaks are estimated using 10 percent of the average Synthetic Organic Chemical Manufacturing Industry (SOCMI) factors. Roche conducts a Leak Detection and Repair (LDAR) program in accordance with the 40 CFR Part 63 Subparts H and I MACT testing and repair standards to justify this approach. Storage tank emissions are estimated using the EPA's TANKS Program, Version 2.0 or newer. Wastewater treatment emissions are estimated using the EPA's SIMS program (Version 2.0 or newer), and data obtained from periodic water sampling. Emissions from fuel burning at the thermal oxidizer are estimated using AP-42 factors. Emissions from the cold cleaners are based on solvent consumption data.

V. Compliance Status

The Division believes that these sources were in compliance with all applicable requirements as of the date of application, except where construction permits were in process of being issued. Issuance of this operating permit brings the sources into compliance with construction permit requirements.

VI. Alternate Operating Scenarios

The following Alternate Operating Scenarios are permitted at this facility.

- 1. The permittee may shift equipment/processes within the facility or add new processes/products provided the provisions listed under Operational Flexibility, below, are met.
- 2. The permittee may use the ECS to comply with Regulation No. 7 requirements. A log indicating when the ECS is used to meet Regulation No. 7 requirements shall be maintained. The ECS must be operated at a certain minimum temperature and residence time. Monitoring is performed as described for the ECS, above.
- 3. The permittee may use pilot plants, laboratories, or testing centers for commercial production purposes, or exceed the construction permit de minimis emission levels, provided the facility wide emission limit is met and all other procedures listed under Operational Flexibility, below, are met.
- 4. The permittee currently does not use benzene in amounts that are subject to 40 CFR Part 61 requirements (National Emission Standards for Hazardous Pollutants). The following requirements are included in the operating permit, in the event allowed changes at the facility cause equipment to become subject.
 - 40 CFR Part 61, Subpart FF, National Emission Standard for Benzene

Waste

- 40 CFR Part 61, Subpart J, National Emission Standard for Equipment Leaks (Fugitive Emission Sources) of Benzene
- 40 CFR Part 61, Subpart V, National Emission Standard for Equipment Leaks (Fugitive Emissions)

These subparts contain specific monitoring and recordkeeping requirements.

- 5. The permittee may burn other clean fuels besides natural gas in the thermal oxidizer (ECS) (including the back-up thermal oxidizer, see Alternate Operating Scenario 6), provided all applicable requirements in the operating permit are met, and no new applicable requirements are triggered.
- 6. The permittee may install and use a back-up thermal oxidizer, provided it is designed with an equal or smaller heat input rating, and minimum combustion temperature and residence time equal to the existing unit. Only one thermal oxidizer will be used at a time, except for overlap during startup or shutdown. Emission and performance tests are required within 60 days after maximum production rate is achieved.
- 7. The permittee does not currently recover solvents on-site for commercial sale. The permittee may recover, store and transfer solvents for commercial sale to other commercial facilities where the solvent can be reused, thus minimizing the waste transported offsite for disposal, provided that the following requirements, where applicable, are met:
 - 40 CFR Part 60, Subpart Kb Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984
 - 40 CFR Part 60, Subpart VV Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry
 - 40 CFR Part 60, Subpart NNN Standards of Performance for Volatile Organic Compound (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations
 - 40 CFR Part 61, Subpart V National Emission Standards for Equipment Leaks (Fugitive Emission Sources)
 - 40 CFR Part 63, Subpart F National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry
 - 40 CFR Part 63, Subpart G National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater

These regulations set forth specific monitoring, recordkeeping, and reporting

requirements that must be met. The addition of solvent recovery at this facility will not be a major modification in itself for PSD/NSR purposes.

VII. Pre-approved Reasonably Available Control Technology, and Emission Control Efficiency for New Equipment

New equipment added to the facility that is not pre-approved by an Alternate Operating Scenario is subject to permit modification requirements. This permit establishes Federally enforceable requirements for several stringent control efficiency scenarios. Reasonably Available Control Technology (RACT), per the requirements of Colorado Regulation No. 7, Section XIV, is considered to be equivalent to 90% control for the pharmaceutical industry according to EPA guidance documents. Also, according to EPA guidelines, thermal oxidizers which meet requirements prescribed for Roche Colorado Corporation are considered to achieve a minimum of 95% efficiency. This allows the permittee to use 90% or 95% control efficiency in calculating the potential to emit for new equipment, depending on the control efficiency scenario being employed, for purposes of determining which operating permit modification procedure (minor or significant) applies. The monitoring and recordkeeping procedures set forth in the operating permit must be met for all new equipment. The operating permit includes this allowance and requirement. This provision is included for emission calculations only. All other applicable requirements must be addressed in the permit modification application.

In addition, new equipment added to this facility is subject to Colorado Regulation No. 7 RACT requirements. RACT is a case by case determination, and according to Colorado Regulation No. 3, Part C, does not qualify as a minor permit modification. Some new equipment. Such as pharmaceutical synthesis equipment, is subject to specific RACT provisions set forth in Regulation No. 7, therefore a case by case RACT determination is not required, and this type of new equipment may be processed under the minor permit modification procedures. Other new equipment may not be subject to existing specific RACT provisions, and would therefore require a case by case determination. For this facility, however, the Division is pre-determining RACT for such new equipment to be 95% control of emissions. Therefore, new equipment meeting the pre-determined RACT, 95% control requirement may qualify for the minor modification procedure, provided all other minor permit modification criteria are met. Finally, in cases where case by case RACT or specific RACT requirements are not triggered, the site may utilize a 95% control efficiency to calculate potential emissions for purposes of determining permit modification procedures when employing the thermal oxidizer as emission control.

VIII. Operational Flexibility

Pharmaceutical companies make numerous, frequent changes at their facilities, to address the demand for changing products. Construction Permit 93BO833 recognized this need for flexibility, and provided for the addition of new products and reconfiguration of existing equipment, provided certain notification requirements were met. In addition, the EPA provided for operational flexibility in the pharmaceutical MACT. This operating permit will

be revised or modified in the future to incorporate the MACT operational flexibility provisions. In the interim, the operating permit incorporates the following operational flexibility provision. (Note that Colorado Regulations do not allow for the addition of new equipment without prior review or notification under the applicable construction permit, combined construction/operating permit, or operating permit procedures. The operating permit rules allow for addition of new equipment with the potential to emit up to the PSD significant emission level under the minor modification procedures. Under the minor modification procedures, the permittee may implement a qualifying change as soon as the Division receives a modification application, prior to a revised operating permit being issued. This provides flexibility for adding some new equipment to the facility.)

The permittee may shift equipment within the facility and/or add new processes, and may implement any of the Alternate Operating Scenarios listed above provided the following provisions are met:

- the facility wide VOC emission limit is met
- actual Hazardous Air Pollutant (HAP) emission increases from any new process shall not exceed the de minimis emission rates specified in Regulation No. 3, Part A, Appendices A and D The de minimis levels in these appendices were developed based on relative toxicity of the pollutants. Therefore, this requirement will ensure that the relative toxicity of any new HAP will be equal to or less than that from an existing process.

Prior to shifting equipment or changing processes/products, the permittee must:

- ensure the facility wide VOC emission limit is met
- ensure new HAP emission increases do not exceed the de minimis emission rates
- identify all applicable requirements and associated control equipment parameters
- ensure all applicable requirements will be met

The permittee will maintain an up-to-date log, tracking shifts in equipment and new processes, and all relevant compliance and monitoring information.

The permittee will submit a semi-annual report describing all changes/additions made during the last six months, updated equipment list, control equipment, and emission factor information, applicable requirements, and compliance information.

The Appendices to this operating permit contain "baseline" lists of equipment configurations, products, and emission factors. These appendices are updated every six months, to reflect changes.

IX. Short Term Limits

On April 16, 1998 the Colorado Air Quality Control Commission directed the Division to implement new procedures regarding the use of short term emission and

production/throughput limits on Construction Permits. These procedures are being directly implemented in all operating permits that had not started their Public Comment period as of April 16, 1998. All short term emission and production/throughput limits that appeared in the construction permits associated with this facility that are not required by a specific State or Federal standard or by the above referenced Division procedures have been deleted and all annual emission and production/throughput limits converted to a rolling 12 month total. Note that, if applicable, appropriate modeling to demonstrate compliance with the National Ambient Air Quality Standards was conducted as part of the Construction Permit processing procedures. If required by this permit, portable monitoring results and/or EPA reference test method results will be multiplied by 8760 hours for comparison with annual emission limits unless there is a specific condition in the permit restricting hours of operation.

The following table lists the short term limits that were included in the Construction Permits

but not included in the Operating Permit.

SOURCE	CONSTRUCTION PERMIT NUMBER	SHORT TERM LIMIT
T100 - Tank Farm	84BO333V	6,000 gallons/day chemical throughput
		36.60 lbs VOC emissions/hour
S500 - Thermal Oxidizer 958	95BO1113	Hourly Emissions: 0.22 lb PM 0.22 lb PM ₁₀ 0.01 lb SO ₂ 4.50 lbs NO _x 5.90 lbs VOC 2.50 lbs CO
		16,020 scf natural gas/hour

X. Accidental Release Program - 112(r)

The Title V application reports the facility is not currently subject to the provisions of the Accidental Release Plan provisions of 112(r)(7) of the Clean Air Act, but may be in the future.

Section 112(r) of the Clean Air Act mandates a new federal focus on the prevention of chemical accidents. Sources subject to these provision must develop and implement risk management programs that include hazard assessment, a prevention program, and an

emergency response program. They must prepare and implement a Risk Management Plan (RMP) as specified in the Rule.

Section 68.215(e) of the Federal Clean Air Act requires the Division to address four issues in regards to operating permit sources subject to 112(r):

1. Verify source submitted and register an RMP by deadline

EPA has set up a Website specifically for 112(r) plans. All 112(r) sources will electronically submit their plans to this "designated central location". The Division will require sources to certify in their annual compliance certification that they are/are not subject to 112(r) and they have/have not submitted a Risk Management Plan (RMP) to the designated central location by June 20, 1999 (or on the date the facility becomes subject). In addition, the Division will check the 112(r) website to verify that a RMP was actually submitted to the website by the deadline. Failure to submit a RMP by the deadline by sources subject to 112(r) will be considered a permit deviation for reporting purposes under Title V.

2. Verify that source owner/operator has submitted a source certification or in its absence has submitted a compliance schedule.

As mentioned above, the Division will require that sources certify in their annual compliance certification that they are/are not subject to 112(r) and they have/have not submitted a Risk Management Plan (RMP) to the designated central location by the deadline. If they are subject to 112(r) but did not submit an RMP on time, a compliance schedule under the provisions of Title V must be submitted to the Division by the source. Failure to submit a RMP or a compliance schedule by the deadline by sources subject to 112(r) will be considered a permit deviation for reporting purposes under Title V.

3. For some or all sources use one or more mechanisms such as completeness check, source audits, record review, or facility inspections to ensure permitted sources are in compliance with the requirements of this part

The Division may choose to perform any or all of the activities listed under this subsection. Although there is no specific number of such actions required in the 112(r) rule, a June 3, 1997 draft 112(r) implementation guidance from EPA states that "Congress considered a requirement that 1.4 percent of the RMPs be audited annually, but dropped that provision."

The Division will, at a minimum, perform a "completeness check" on an unspecified number of Title V 112(r) sources. The website that EPA is in the process of developing to accept 112(r) RMP's will include software that will electronically conduct a completeness check on the RMP's. For the purposes of this operating permit, such check shall serve as the completeness check required under 68.215(e)(3). As noted in the Preamble to the final 112(r) rule (June 20, 1996 Federal Register, page 31691), "EPA agrees that the review for quality or adequacy of the RMP is best accomplished by the implementing agency..." In Colorado, the implementing agency is the U.S. EPA. If the EPA website software indicates

that a source did not submit a complete plan, it will be considered a permit deviation for reporting purposes under Title V and the Division may initiate an enforcement action for failure to meet the Title V permit condition (see below). Per the Preamble (page 31691), the Division may perform the completeness checks in a timeframe consistent with the source's Title V certifications.

4. Initiate enforcement action as necessary

This refers to enforcement under Title V, not under Part 68 (112(r)). If a source fails to file a RMP or a compliance schedule by the June deadline or the EPA software indicates that the RMP is not complete, it will be considered a permit deviation for reporting purposes under Title V and the Division may initiate an enforcement action.